

510(k) Summary

AUG 8 2013

Owner/Manufacturer: Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215

Contact Person: Tina O'Brien
Senior Regulatory Affairs Specialist
Phone: (303) 239-2082

Date of Summary Preparation: June 11, 2013

Trade Name: Spectra Optia® Apheresis System

Common Name: Apheresis System

Classification Name: Automated Blood Cell Separator

Product Code: LKN

Predicate Device: Spectra Optia Apheresis System (K071070)

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) sterile, single-use, disposable tubing sets and, (3) embedded software.

A software modification and new disposable connector have been made to accommodate single-needle access for Therapeutic Plasma Exchange (TPE) procedures on the Spectra Optia system. This additional access option does not alter the operating parameters or performance of the Spectra Optia system.

Intended Use:

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis and may be used to perform Therapeutic Plasma Exchange (TPE) procedures.

Technological Comparison:

The system's base technology is not changed by this modification to the Spectra Optia filler. Refer to Table 1 for a comparison of technological characteristics.

Table 1: Key Similarities – Spectra Optia system - TPE with Single Needle Access (subject) vs. TPE with Dual Needle Access (predicate)

Attribute		Comparison
1	Intended Use / Labeling	The Spectra Optia system with single-needle access has the same intended use as the predicate device

Attribute		Comparison
2	Essential Technology	The essential technology of the Spectra Optia system has not changed – it remains an automated blood cell separator and achieves its essential function (the separation of blood cells and plasma) through centrifugation.
3	Materials	The blood-contacting disposable tubing sets are comprised of the same biocompatible materials as previously cleared Spectra Optia disposables.
4	Sterility / Manufacturing	The single-use, sterile disposables are sterilized using the same packaging and validated ETO-based sterilization method, as other cleared Spectra Optia disposables. Likewise, manufacturing methods for the disposables are similar.
5	Clinical Performance	The safety and efficacy of the Spectra Optia system TPE protocol with single-needle access was validated through a laboratory non-inferiority study to compare the plasma removal efficiency (PRE) of the TPE procedure of single-needle vs. dual-needle access. Study results successfully demonstrated non-inferiority between single-needle and dual-needle options for the Spectra Optia Apheresis System's Therapeutic Plasma Exchange protocol in terms of the efficiency of plasma removal. The study also demonstrated that neither the hematocrit of the processed blood nor the rate at which the blood is processed (Inlet Flow Rate) is impacted by the type of venous access (single-needle vs. dual-needle) used to conduct a TPE procedure.

Discussion of Non-clinical Data:

The new Single-Needle Connector and modification to the Spectra Optia's software to support single-needle access were verified through the following activities:

- Physical testing for the Single-Needle Connector focused on testing of the connector's tortuous pathway.
- The modified Spectra Optia system software was verified via Control, Safety, Functional, Reliability, Usability, Exploratory, and Robustness testing.

Discussion of Clinical Data:

Laboratory testing was conducted to verify and validate the functionality and effectiveness of the single-needle access option for TPE procedures on the Spectra Optia system. Clinical validation data were not necessary, based on an analysis of clinical evidence on the use of single-needle access in apheresis procedures and the fact that the modification did not impact the implementation, control, or effectiveness of the system for the system's intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 8, 2013

Terumo BCT, Inc.
% Tina O' Brien
Senior Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215

Re: K131744
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: July 11, 2013
Received: July 12, 2013

Dear Tina O' Brien,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

TERUMOBCT

Spectra Optia® Apheresis System
Therapeutic Plasma Exchange with Single-Needle Access
Traditional 510(k) Submission

4 Indications for Use Statement

Indications for Use

510(k) Number (if known): K131744

Device Name: **Spectra Optia® Apheresis System**

Indications for Use:

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis and may be used to perform Therapeutic Plasma Exchange (TPE) procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
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